

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 25 APR 2006

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Applicant's or agent's file reference JP802777/142	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. <b>PCT/NZ2004/000323</b>	International filing date (day/month/year) 16 December 2004	Priority date (day/month/year) 19 December 2003	
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <b>A61L 15/32</b> (2006.01), <b>A61K 38/00</b> (2006.01), <b>A61L 26/00</b> (2006.01) <b>A61K 9/70</b> (2006.01) <b>A61K 38/17</b> (2006.01) <b>A61P 17/02</b> (2006.01)			
Applicant <b>KERATEC LIMITED et al</b>			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 11 July 2005	Date of completion of this report 06 April 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer <i>Arati Sardana</i> <b>ARATI SARDANA</b> Telephone No. (02) 6283 2627

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on:

- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages **1, 2, 5-20 and 24** as originally filed/furnished
- Pages **3 and 4** received by this Authority on **18 October 2005** with the letter of **18 October 2005**
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_

- ☒ the claims:
- pages **22 and 23** as originally filed/furnished
- pages\* as amended (together with any statement) under Article 19
- pages\* **21** received by this Authority on **18 October 2005** with the letter of **18 October 2005**
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_

- ☒ the drawings:
- pages **1/3-3/3** as originally filed/furnished
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 15, 18, 19, 21 and 22	YES
	Claims 1-14, 16, 17 and 20	NO
Inventive step (IS)	Claims	YES
	Claims 1-22	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

**CITATIONS:**

**D1: WO 2003/011894**

**D2: US 5,932,552**

**D3: WO 2003/103737**

**D4: AU 2002330798**

**EXPLANATION:**

**D1** discloses the production soluble keratin derivatives. The keratin protein fraction that is produced is intact and are S-sulfonated keratin intermediate filament proteins and S-sulfonated keratin high sulphur proteins.

**D2** discloses keratin hydrogel which can be used as a wound dressing. The disulfide linkages in keratin are reformed.

**D3** discloses keratin material that is S-sulfonated and enriched in intermediate filament proteins. D3 further discloses S-sulfonated keratin intermediate filament protein powder. The keratin material disclosed in D3 is used in the treatment of bone fractures.

**D4** discloses the production of keratin derivatives of the present invention in the form of films, fibers, foams and adhesives and an extension of the use of these in medical materials.

**NOVELTY (N) Claims: 1-14, 16, 17 and 20**

Claims 1-8 are not novel in light of the disclosure of D1, D3 or D4 because the phrase 'a material for treating a wound' renders keratin protein fraction to be only suitable for treating wounds. Therefore keratin protein fractions of D1, D3 or D4 that are suitable for such use deprive claims 1-8 of their novelty. Claim 9 is not novel in light of the disclosure of D4 which discloses a fiber, film or a foam of the present keratin protein fraction. Claims 1, 10-14, 16, 17 and 20 are not novel in light of the disclosure of D2 which discloses intact keratin protein fraction containing wound hydrogel. D2 further discloses that formulation of hydrogel involves treating keratin with reductant ammonium thioglycollate. Therefore claims 1, 10-14, 16, 17 and 20 lack novelty.

**INVENTIVE STEP Claims 1-22**

Claims 1-14, 16, 17 and 20 as for novelty. Claims 1-22 lack inventive step in light of the disclosure of D1, D3 or D4 when combined with the disclosure of D2. The skilled person would formulate the wound dressing or hydrogel of D2 by substituting the keratin of D2 with keratin protein fraction of D1, D3 or D4. Therefore claims 1-22 lack an inventive step.